First Named Inventor: Andrew Clark

## **REMARKS**

This is in response to the Office Action mailed on March 20, 2008, in which pending claims 1-19 and 36 were rejected pursuant to 35 U.S.C. §102(e). Specifically, claims 1-19 and 36 were rejected under 35 U.S.C. § 102(e) as being anticipated by Stark et al. (U.S. Patent Publication 2006/0181678 A1). In view of the following remarks, reconsideration and allowance of all pending claims (1-19 and 36) is requested.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Thus, for a reference to anticipate an invention, the reference must disclose each and every element present in the claims. The identical invention must be shown in as complete detail as is contained in the claim. M.P.E.P. §2131.

The Office Action states that pending independent claims 1 and 36 (and all claims dependent on those claims) are anticipated by Stark et al. (US 2006/018678). In order for the invention as claimed in Claims 1 and 36 to be anticipated by Stark, Stark must provide, "processing software which receives data from the image capturing means, and which processes said data according to an algorithm to establish the distance between the surface of the eyeball and the image capturing means." (emphasis added). It is respectfully submitted that Stark does not provide processing software which processes data according to an algorithm to establish the distance between the surface of the eyeball and the image capturing means.

In the sections of Stark referred to in the Office Action (namely sections 0077, 0079 and 0080) as disclosing the above-mentioned feature, there is no reference to "establishing the distance between the surface of the eyeball and the image capturing means." There are two ways in which pupil size may be established. Either, at least one real parameter must be measured, in which case it may be possible to derive real pupil size (as is the case for the present invention), or

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the magnitude of at least one parameter must be assumed, in which case any pupil size or change in size derived is an assumed pupil size.

In Stark, the calibration and pupil identification processing techniques are described in paragraphs 0119, 0120 and 0121. As stated in paragraph 0119, the process is the same for all embodiments of the invention described in Stark. The derived pupil size is based on an assumption that the horizontal diameter of the sclera/iris border is a certain size, e.g. 11.7 mm or another selected size between 10 and 12 mm. When an image of the sclera/iris border is obtained, the number of pixels defining the horizontal diameter of the sclera/iris border is divided by the assumed horizontal diameter. This generates a distance value for the width of each pixel. The pupil diameter may then be established by multiplying the number of pixels representing the diameter of the pupil by the pixel size derived as set out above from assumed data. As stated in paragraph 0097 of Stark, the flying spot algorithm bases measurements on numbers of pixels, not actual distances, i.e. distance values are derived from the assumed horizontal diameter to the sclera/iris border.

Compare this with the current applicant's disclosure and claims. For example, in one embodiment of the present invention, the algorithm establishes the distance between the surface of the eyeball and the image capturing means by measuring the distance between highlights detected on the eye surface. From this <u>measured distance</u>, distance to the image capturing means can be calculated using trigonometry embodied in the algorithm (see paragraph 7 of page 13 of the application as filed).

Hence, Stark does not disclose any processing software that receives data from the image capturing means, and by processing said data according to an algorithm establishes the distance between the surface of the eyeball and the image capturing means, and as such the invention as claimed in Claims 1 and 36 is not anticipated by Stark. M.P.E.P. §2131. Because Claims 2-19 each depend from allowable independent Claim 1, the dependent claims are also allowable.

Further, Stark requires circular targets on the reticle 30 are provided such that they are concentric with the pupil and eye under observation (see paragraph 0049), or, where there is no direct view of the eye (as for pupilometers 300, 400) the provision of graphic aides such as crosses or boxes. If the pupil is not aligned with the graphic aides the pupilometer determines that it is not properly positioned and the user is prompted to reposition the pupilometer. The pupilometer of the present invention does not require such accurate positioning with respect to the eye being examined. To position the pupilometer of the present invention such that the pupilometer may function, all that is required is for the pupilometer positioned within a range of distances rmin to rmax from the surface of the patient's eye. The pupilometer of the invention need not be aligned so accurately with the pupil of the patient as is required by Stark. This is particularly advantageous where the pupilometer is being used by paramedics, where it is important to conduct tests without moving the patient.

It would not be obvious to arrive at the features of the invention as claimed in Claims 1 and 36 from the disclosure of Stark. Whilst Stark recognizes the desirability of reducing the restrictions on orientation of a hand-held pupilometer (see paragraph 0010), positioning of the Stark pupilometer relative to the pupil is nevertheless restricted.

Furthermore, there is nothing to suggest to one skilled in the art that establishing actual dimensions of features of the eye is desirable. A pupilometer is used *inter alia* in the neurological assessment of unconsciousness, for early recognition of neurological deterioration in situations where intra-cranial pathology is a threat, for assessing eye shape and condition, monitoring tiredness, and in the detection of drugs and alcohol in a person (see page 1 of the application as filed). In use a pupilometer measures responses to stimuli. In order to measure accurately responses to stimuli it is necessary to base measurements of changes on accurate measurements of the patient's eye. However, Stark relies on assumed sizes, and hence cannot provide the accuracy and therefore reliability of result when compared with the pupilometer of the present invention. Where a pupilometer is being used for the aforementioned purposes the result is vitally important.

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## Conclusion

The present application, including pending claims 1-19 and 36, is now in condition for allowance. Notice to that effect is respectfully requested.

The Examiner is cordially invited to contact the undersigned at the telephone number listed below if such a call would in any way facilitate the allowance of this application.

The Commissioner is authorized to charge any additional fees associated with this paper or credit any overpayment to Deposit Account No. 11-0982.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: August 20, 2008 By: /Larrin Bergman/

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